

REMARKS

Telephonic interview

Insofar as this application appears to be in condition for allowance save for a few minor issues, Applicants request a telephonic interview with the Examiner prior to the examination of the claims on their merits.

Claims

Claims 1, 4–19 and 21–23 are pending. Claims 1, 4–11 and 21–23 are under consideration and claims 12–19 are withdrawn from consideration due to restriction/election, pursuant to the restriction requirement mailed November 21, 2007.

Claims 2, 3 and 20 are cancelled without prejudice or disclaimer.

Applicants gratefully acknowledge the allowability of claims 4, 5 and 20. Since the claims are now limited to the subject matter which has been allowed, all rejections are moot. Applicants' amendment of the claims is not to be construed as acquiescence to any rejection.

Amendments

Claims 1 and 11 have been amended to expressly recite the reagents used in the determination step. No agreement is to be implied.

Claims 9–10 are amended as per the Examiner's suggestion.

It is respectfully submitted that the amendments do not recite new matter. Entry thereof is respectfully requested.

Claim objection

The objection of claims 9 and 10 is moot in view of the foregoing amendments.

Sustained Rejection under §112, ¶2

Claims 11 and 21–23 are rejected under this section for allegedly being indefinite. This rejection is respectfully traversed.

The Examiner contends that the claimed subject matter is incomplete for omitting essential steps. Applicants respectfully disagree with the Examiner's contention. However, claim 11 has been amended to expressly recite the relation between method steps (a) and (b). Favorable reconsideration is respectfully requested.

The Examiner's contention that the claimed subject matter is indefinite with respect to the claim term "lower level" is respectfully traversed. To a skilled biochemist who possesses the tools

and knowledge on antibody-based detection assays, the meaning of the term is clear and definite. Such levels can be determined, for example, via direct immuno-blotting techniques, ELISA assays, or other indirect (for e.g., chemi-luminescence based) assays. See claim 8, for example. Contrary to the Examiner's assertions, Applicants submit that based on the detailed disclosure provided in the specification, a skilled artisan has a definite understanding of the metes and bounds of the claimed invention. For example, reference samples are described in paragraph [0014] of the published specification. HDAC inhibitors are described in, for example, paragraphs [0006] to [0008] of the published specification. The antibody molecules and binding specificity thereof are further provided. See for example, paragraphs [0039] to [0040] of the published specification. The PTO's contentions of indefiniteness are therefore without merit.

The Examiner is further requested to reconsider the rejection in view of the fact that the Courts have long held that "The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles...Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite." *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004) (Emphasis added). The Office Action has not demonstrated that the claimed elements, for example, the use of HDAC inhibitors and/or antibody molecules, renders the claims insolubly ambiguous. Withdrawal of the rejection is respectfully requested.

New rejection under §112, ¶2

The rejection of claims 1, 4–11, and 21–23 under this section is respectfully traversed.

With respect to the contentions raised under item 13 (a) of the Office Action, the Examiner is cordially requested to review the foregoing arguments.

With respect to the contentions raised under item 13(b) of the Office Action, Applicants traverse the requirement that the identity of the HDAC inhibitor (and relationship thereof with respect to the inhibitor recited in independent claim 1) be expressly recited in the claims. Such is not necessary at all. For example, the two different concentrations or dosages of the same HDAC inhibitor can be examined in accordance with the claimed invention. See, the disclosure in the Examples, particularly paragraph [0108] of the published specification. Likewise, two different HDAC inhibitors can be studied with respect to their efficacy. See the disclosure in Example 4.

Antecedent basis

Applicants thank the Examiner for his careful review of claim 11. The foregoing

amendments render this rejection moot.

Insofar as claim 11 recites a conjugate in (a) (iii), claims 21–23 which dependent thereon and further recite the features of such conjugates, are compliant under 35 USC §112, ¶4.

Withdrawal of the rejection is respectfully requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

Respectfully submitted,

/Sagun KC/

Sagun KC, Reg. No. L0510
For Applicant(s)

/Anthony J. Zelano/

Anthony J. Zelano, Reg. No. 27,969
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: LEDER-0014

Date: December 14, 2009